



# GUIDELINES ON CUMULATIVE RISK ASSESSMENT

**Risk Assessment Forum request to the  
Science and Technology Policy Council for  
concurrence on external peer review**

September 2, 2020

David Bussard, ORD, RAF Chair  
Wendy O'Brian, R8, Technical Panel Chair  
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- ▣ STPC External Review Concurrence Package
  - Draft CRA Guidelines for external peer review
  - One-page overview of CRA Guidelines
  - Charge questions for CRA Guidelines peer reviewers
  
- ▣ CRA Guidelines are an Agency Goal
  - Administrator & Science Policy Council: CRA Planning and Scoping, 1997
  - Follows and develops 2003 Framework for CRA
  - NRC recommendations to EPA (*Phthalates CRA*, 2008, *Science & Decisions*, 2009)
  - STPC charge to RAF for CRA Guidelines, 2016

The Food Quality Protection Act specified cumulative risk assessments of pesticide chemicals with a common mechanism of toxicity; and the Safe Drinking Water Act specified the assessment of cumulative risks from disinfection by-products in drinking water.

# STPC Charge to RAF



Charge to the RAF from the STPC on June 3, 2016:

- ▣ The Panel will plan and complete a module on CRA planning, scoping and problem formulation.
- ▣ The Planning Module will update and revise the Science Policy Council 1997 *Guidance on Cumulative Risk Assessment. Part 1. Planning and Scoping.*
- ▣ The Panel will assign a writing team to prepare the Planning Module, consistent with insights and recommendations resulting from the 2014 RAF CRA Colloquium.
- ▣ The document will draw on recent EPA publications and other sources identified by the Panel, and shall include an introduction, as well as sections on planning, scoping and problem formulation.

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## ▣ CRA Planning, Scoping and Problem Formulation

- Updates 1997 SPC Guidance on CRA Planning and Scoping
- Clarifies CRA planning steps with greater detail
- Revises general statements of agency-wide goals with a "fit for purpose" strategy for CRA design that incorporates improved problem formulation and recognizes diverse applications and outcomes for CRAs



- The 1997 Guidance is updated with Guidelines that replace declarative statements such as “managers need to place special emphasis on *cumulative risk*” with recommended steps for when to consider a CRA suitable and feasible, and the range of considerations that may be appropriate in planning and problem formulation.
- The Guidelines reframe consideration of non-chemical stressors as stand-alone factors to possible modifiers of exposure and response to identified chemical stressors of concern.



- ▣ RAF appointed review team provided approval of the product – May 2020
- ▣ Next step: STPC concurrence on draft guidelines for external peer review
- ▣ August 5, 2020 CRA Guidelines to SSP
  - Two-week program office review for show-stoppers
- ▣ September 2, 2020 – CRA Guidelines to STPC
  - Request concurrence for external peer review